IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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November 9, 2011

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Serial No. : 10/566,826

Applicants : Akio KIMURA et al.

Filed : January 31, 2006

For : PROSTAGLANDIN-CONTAINING PRODUCT

Art Unit : 1618

Examiner : Jake Minh VU

Docket No. : 06067/HG

Confirm No. : 8012

Customer No.: 01933

PRE-APPEAL BRIEF CONFERENCE REQUEST

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

S I R :

Review of the rejection in the above-identified application is respectfully requested. No amendments are being filed with this request. This request is being timely filed with a Notice of Appeal.

The review is requested for the reasons set forth on the following five pages of explanation.

Claims 12 and 14 are pending for action. The other claims are either canceled or withdrawn. Claims 12 and 14 were rejected under 35 USC 103 in the August 12, 2011 Office Action as being unpatentable over Morishima et al. (WO 02/22131 (US 2004/0097592 being used as a translation)) in view of Koide et al. (JP 7-33650). As detailed below, the teaching in the art fails to support the rejection.

A primary object of the presently claimed invention is to significantly inhibit a decrease of the content of a prostaglandin F2α isopropyl ester contained in the container by the selection of materials from which the container is made. Applicants' claim 12 names several prostaglandins; applicants' claim 14 names one prostaglandin. Both claims 12 and 14 have the same requirement for the composition of the container

It appears from the August 12, 2011 Office Action that the position was taken that since the present claim recites "comprising" and does not exclude a nonionic surfactant or an antioxidant, it would be obvious for one of ordinary skill in the art to include a composition comprising a prostaglandin disclosed by Morishima et al. in a resin container (for example, Comparative Example 4) of Koide et al. comprising polyethylene terephthalate and polyarylate.

The Morishima et al. reference was cited to teach prostaglandin F2α derivatives. The Koide et al. reference was cited with respect to a composition of a container, and a generic disclosure of inhibiting photolysis and adhesion of Vitamin A to the container. It was admitted on page 5, lines 3 to 4 of the March 15, 2011 Office Action that the references do not specifically teach combining the ingredients in the claimed amounts to form the container.

At the top of page 4 of the March 15, 2011 Office Action, it was stated that paragraph [0014] of Morishima et al. teaches "polyethylene terephthalate" and "acrylic resins." Acrylic resins fail to meet applicants' claim requirement of a polyacrylate component. Namely, "acrylic resins" are resins comprising a polymer of acrylic acid or

acryl ester (CH_2=CHCOOR, R=H, alkyl and the like); a "polyarylate" is a polymer which differs completely from the structure of "acrylic resins" (see the paragraph bridging pages 4 to 5 in applicants' RESPONSE UNDER 37 CFR 1.111 filed June 13, 2011). Thus, the "acrylic resins" and applicants' claim requirement of "polyarylate," are completely different resins.

Morishima et al. do not recognize the importance of the container composition to resolve the problem to inhibit the absorption of prostaglandin derivatives to a container. Rather, Morishima et al. require an addition of a nonionic surfactant or an antioxidant to inhibit the absorption.

In contrast to the presently claimed invention, Morishima et al. do not teach or suggest that the storage of a prostaglandin derivative in a container made of a polymer alloy of polyethylene terephthalate and polyarylate inhibits the decrease of the content of the prostaglandin derivative.

Koide et al. was relied on by the Examiner with respect to the composition of the container. However, although Koide et al. is concerned with the problem of stability to light and therefore teach storing the Vitamin A in a container made of polyethylene terephthalate containing (1) a pigment or (2) pigments and a U-polymer, wherein a pigment is an essential component and a U-polymer (polyarylate) is an optional component.

Koide et al. require storage of stabilized vitamin A in a container made of polyethylene terephthalate containing a pigment to stabilize vitamin A, which is unstable to light. In contrast thereto, the presently claimed invention involves storage of a composition comprising a prostaglandin derivative in a container made of a polymer alloy of polyethylene terephthalate and polyarylate to inhibit the absorption of a prostaglandin derivative to a container. Koide et al. and the presently claimed invention differ from each other not only in the target drugs, but in their respective objects.

Since the stabilizing effect of vitamin A to light, and the absorption inhibiting effect of a prostaglandin derivative, which is liable to be absorbed on a container, are completely different from each other, it is respectfully submitted that the Examiner judged the obviousness of the presently claimed invention based on a misunderstanding of the presently claimed invention and Koide et al.

Also, Koide et al. do not teach or suggest that storing vitamin A (or a prostaglandin derivative) in a container made of a polymer alloy of polyethylene terephthalate and polyarylate would inhibit the decrease of the contents therein.

Koide et al. do not teach or suggest that the composition of the container alone can stabilize the contents in the container. In fact, the opposite is true. Examples 1 and 2 in Table 1 of Koide et al. show that when Vitamin A palmitate is stored in a resin container comprising polyethylene terephthalate containing a pigment, the concentration (residual ratio) of the Vitamin A are respectively 89% and 99%, and the Vitamin A palmitate is stable. In contrast, the concentration (residual ratio) of the Vitamin A palmitate in Comparative Example 1 in Table 1 and Comparative Example 4 in Table 2, wherein the resin does not contain a pigment, are respectively 0% and 26%. Thus, a stabilizing effect for the container alone is not established.

The following was stated at the middle of page 4 of the August 12, 2011 Office Action:

> "...Applicant rebut this explicit teaching in the abstract of the KOIDE reference with Tables 1 and 2 disclosed by KOIDE in Japanese without any English translation. The Examiner suggests Applicant to completely translate Tables 1 and 2 into English, if Applicant wishes to use Tables 1 and 2 as a rebuttal to an explicit teaching as disclosed by KOIDE."

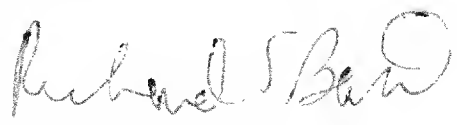
In making the above statement, the Examiner ignored the English-language translation of Koide et al. which he provided with the August 6, 2009 Office Action.

Such English-language translation contains English-language translations of Tables 1 and 2 of Koide et al.

Therefore, Koide et al. and the presently claimed invention completely differ from each other. One of ordinary skill in the art would not expect success for the presently claimed invention from the Koide et al. teaching, even when combining the container of Koide et al. with the drug composition of Morishima et al.

In view of the foregoing, it is respectfully requested that the rejection under 35 USC 103 of claims 12 and 14 is not supported by the art.

Respectfully submitted,



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